



DEPARTMENT OF HEALTH & HUMAN SERVICES

520 9/3/97
PUBLIC HEALTH SERVICE

Food and Drug Administration
Denver District Office
Building 20 - Denver Federal Center
P. O. Box 25087
Denver, Colorado 80225
TELEPHONE: 303-236-3000
FACSIMILE: 303-236-3551

August 11, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

DEN-97-27

Mr. Ralph L. McCormick, Owner
Mc 3x
245 South Main
PO Box 263
Kamas, Utah 84036-0263

PURGED

Dear Mr. McCormick:

An investigation at your beef cattle operation located in Kamas, Utah, was conducted by Consumer Safety Officer Jill A. Mielziner on June 27 and July 3, 1997. The inspection confirmed that you offered an animal for sale for slaughter as food in violation of sections 402(a)(2)(D) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), and that you may have caused animal drugs to become adulterated within the meaning of section 501(a)(5) of the Act.

On or about April 15, 1997, you offered a beef cow for slaughter, identified as USDA case number [REDACTED] to [REDACTED]

[REDACTED] USDA analysis of muscle tissue samples collected from this animal identified the presence of oxytetracycline residue of [REDACTED] ppm. A tolerance of 2.00 ppm had been established for residues of oxytetracycline in the edible tissues of beef cows in Title 21 Code of Federal Regulations Part 556.500 (21 CFR 556.500) at the time the analysis was conducted.

Our investigation revealed the use of [REDACTED] Oxytetracycline HCL. The presence of this drug at the level found in edible tissue from this animal causes the food to be adulterated within the meaning of section 402(a)(2)(D) of the Act.

Our investigation also found that you hold animals under conditions which are inadequate so that diseased and/or medicated animals bearing potentially harmful drug residues may enter the food supply. For example, you lack an adequate system for assuring that animals medicated by you have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. Food from animals held under such conditions are adulterated within the meaning of section 402(a)(4) of the Act.

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You are adulterating the drug [REDACTED] brand of oxytetracycline that your firm uses on beef cows within the meaning of section 501(a)(5) of the Act when you fail to use the drug in conformance with its approved labeling. [REDACTED] is labeled to discontinue use 18 days before slaughter to permit elimination of the drug from edible tissues. Your use of the drug without following the labeled withdrawal period causes the drug to be unsafe to use.

The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for use as food, you are responsible for assuring that your overall operation and the foods you distribute are in compliance with the law.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice such as seizure, and/or injunction.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you caused the adulteration of an animal that was sold and subsequently offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

You should notify this office in writing within 15 working days of the steps you have taken to bring your firm into compliance with the law. Your response should include each step being taken, that has been taken or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 30 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your response should be sent to Shelly L. Maifarth, Compliance Officer, Food and Drug Administration, P.O. Box 25087, Denver, Colorado, 80225-0087. She may be reached at (303) 236-3046 if you have any questions about this matter.

Sincerely,


Gary C. Dean
District Director

cc: Paul E. Thompson
Regional Director
USDA/FSIS, Western Region
620 Central Avenue, Building 2C
Alameda, CA 94501

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[REDACTED]